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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,573	09/23/2003	Jonathan R. Coppeta	17509-0068	3038

29052 7590 09/14/2006

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,573

Applicant(s)

COPPETA ET AL.

Examiner

Elizabeth R. MacNeill

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-29,35,36 and 39-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-29,35,36 and 39-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. This application contains claims drawn to an invention nonelected with traverse in Paper No. 08302006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Allowable Subject Matter

2. The indicated allowability of claim 19 is withdrawn in view of the newly discovered reference(s) to Kriesel (US 6,200,293). Rejections based on the newly cited reference(s) follow.

Response to Arguments

3. Applicant's arguments with respect to claims 14-29,35 and 36 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Art Unit: 3767

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 14 and those dependent from are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over:

Claim 1 of U.S. Patent No. 7,052,488.

Claim 1 of U.S. Patent No. 7,041,130.

Claims 1,22, and 31 of U.S. Patent No 6,849,463.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is simply a broader recitation of a previously claimed invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims are rejected under 35 U.S.C. 102(b) as being anticipated by Santini (US 5,797,898).

Regarding claims 14 and 35, Santini teaches a micro tube array (10) made of a metal or alloy (i.e. silicon), comprising a reservoir (34), a release formulation ("release system containing the drug of other molecule (Fig 1)), a rupturable covering ("reservoir cap material" (Fig 1)) and means for rupturing the covering (i.e. biodegradation or electric conduction)

Art Unit: 3767

Regarding claim 15, the rupturable covering includes defects (i.e. degradable molecules) to facilitate rupture

Regarding claim 22, the release formulation is contained within a rigid reservoir (Fig 1)

Regarding claims 23 and 36, the release formulation is a drug formulation

Regarding claim 24, the cover is a metal foil (i.e. copper or gold)

Regarding claims 25-27, the micro tubes are connected by and extend from a planar base which is made a biocompatible metal (i.e. gold as disclosed) created by an electroplating process

Regarding claim 29, the micro tubes include control electronics (Fig 3)

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 16-20 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini as applied to claim 14 above, and further in view of KRIESEI (US 6,200,293).

Regarding claims 16-20 and 42-47, Santini discloses a micro needle array with a rupturable covering as disclosed above. Santini does not disclose the use of a heat-expandable material used to expel the drug from the micro needle reservoir.

Kriesei teaches the use of heat-expanding material (60) to expel a drug formulation (F) from a reservoir (44) and into a patient, where the drug and expanding material are kept separate (52)

Art Unit: 3767

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the heat expanding material of Kriesei with the microtubule array of Santini in order to "effectively avoid extended flow delivery rate trail-off at the end of the fluid delivery period"

10. Claims 40 and 41 rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Kriesei as applied to claim 16 above, and further in view of THEEUWES (US 4,111,202).

Santini and Kriesei teach the limitations of claim 16 as above, but do not teach the use of a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation.

Theeuwes teaches an osmotic drug delivery system with a semi permeable membrane which allows water or another liquid to diffuse into the expanding material in order to displace and expel the drug formulation (Fig 4)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the osmotic delivery system of Theeuwes with the micro needle array of Santini and Kriesei in order to facilitate expansion of the expandable member without electronics.

11. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini as applied to claim 14 above.

Santini discloses the claimed invention except for the size limitation that the diameter of the micro tube is 0.5mm to 1.0mm. However, Santini does teach that the thickness of the device is up to a several millimeters, specifically having a primary dimension of less

Art Unit: 3767

than 2cm. These dimensions are on the order of a micro tube inner diameter as claimed/ It would have been an obvious matter of design choice to adjust the inner diameter, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CPA 1955)

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini as applied to claim 14 above, and further in view of LLE (US 5,911,737).

Santini discloses a micro needle array with a rupturable covering as disclosed above but does not disclose the use of a shape memory alloy in construction of the micro tube. Lee teaches the use of a shape memory alloy in construction of a micro tube (Col 1 line 25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the shape memory alloy of Lee with the micro tube array of Santini as an alternative material.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 7:00-3:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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9/5/06*

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons